HFI-35 #1901b

DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION
4298 Elysian Fields Avenue
New Orleans, LA 70122-3896
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July 7, 1998

WARNING LETTER NO. 98-NOL-27

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Vernon R. Loucks, Jr., Chairman and CEO
Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

Dear Mr. Loucks:

During an inspection of your firm, located at 911 North Davis Avenue in Cleveland, Mississippi, on March 10-20, 1998, our investigator determined that your firm manufactures medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that your general hospital devices, sterilized by the ethylene oxide process, are adulterated within the meaning of the Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR) Part 820, as follows:

1. Failure to validate a process with a high degree of assurance where the results of a process cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a). For example:

   a) Validation studies for the two ethylene oxide cycles are inadequate to demonstrate that product in the routinely processed 13 pallet loads will be exposed to conditions that will consistently attain the specified level of sterility assurance, in that sufficient qualification runs were not performed under conditions that have been shown to be the same or equivalent to the routine runs.

   b) Ethylene oxide validation studies do not adequately demonstrate that the sterilization process does not adversely affect the packaging.

   c) Documentation is inadequate for the description and identification of the validation test loads used to challenge sterilization cycles 14-03-01-173 and 14-03-01-174.

d) The process challenge device, used in one of the two ethylene oxide cycle validation tests, did not reflect actual device labeling conditions in that it was manufactured without applied unit labeling.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483, issued at the closeout of the inspection, may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts. Additionally, no pending applications for premarket approval (PMA's) or export approval requests will be approved and no premarket notifications (Section 510(k)'s) will be found substantially equivalent for products manufactured at the facility in which the above GMP violation was found until the violation has been corrected.

We again acknowledge your firm's response, dated March 23, 1998, to the inspectional observations listed on the FDA-483 presented at the close of the March 10-20, 1998, inspection. However, the response does not adequately address a number of items, including those described above in this letter.

You should take prompt action to correct the deviation. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be directed to Nicole F. Hardin, Compliance Officer, Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, LA 70122-3896.

Sincerely,

Charles H. Scarbrough for

James E. Gamet
District Director
New Orleans District

Enclosure: FDA-483

cc: Mr. John L. Quick, Corporate Vice-President
Baxter International, Inc.
Route 120 and Wilson Road
Round Lake, Illinois 60073-0490

Mr. Charles D. Miller, Plant Manager
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